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(54) **KNOTLESS GRAFT FIXATION ASSEMBLY**

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See application file for complete search history.

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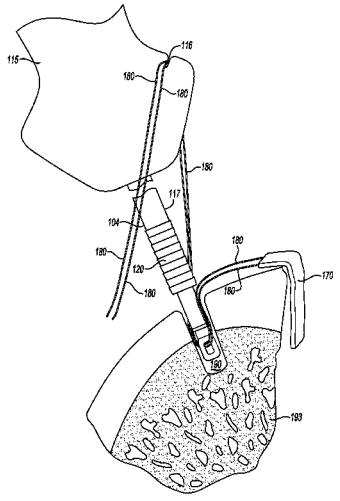
(57) **ABSTRACT**

An illustrative example suture securing assembly includes an inserter having a distal end, a proximal end, and a longitudinal axis between the distal end and the proximal end. A first member includes an eyelet oriented to thread suture across the longitudinal axis. The first member is situated near the distal end of the inserter. The first member is configured to be placed in bone. A second member is situated near the distal end of the inserter. The second member is moveable relative to the first member in a distal direction toward the eyelet into a suture securing position where the second member traps suture.

30 Claims, 14 Drawing Sheets



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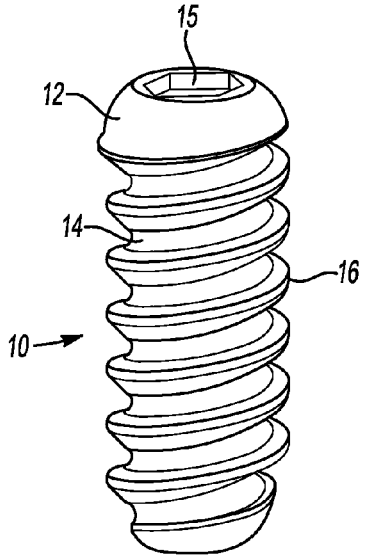

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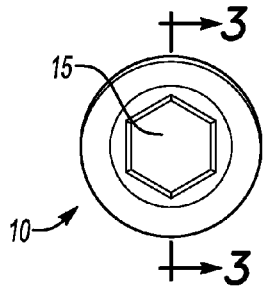

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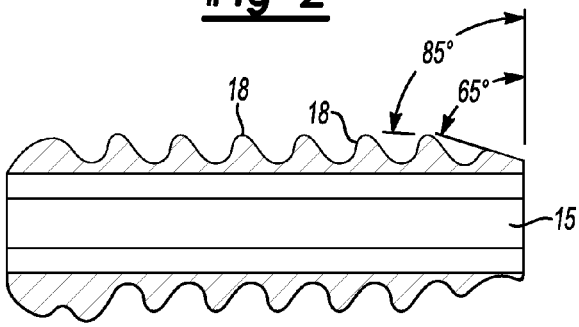

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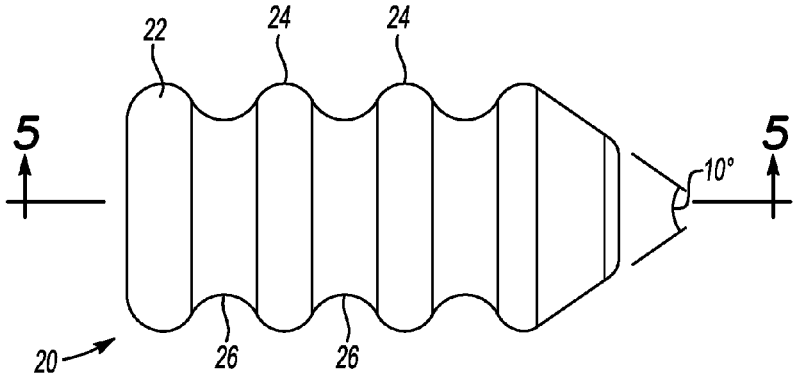

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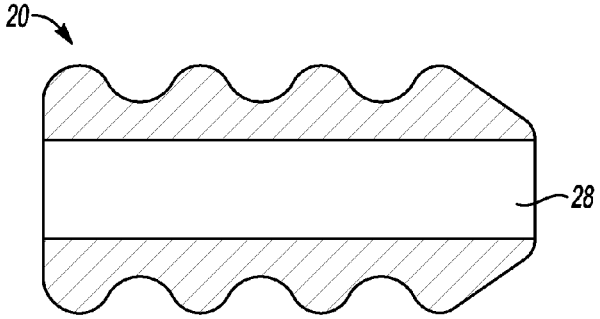

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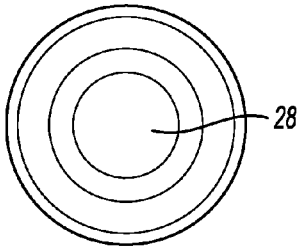

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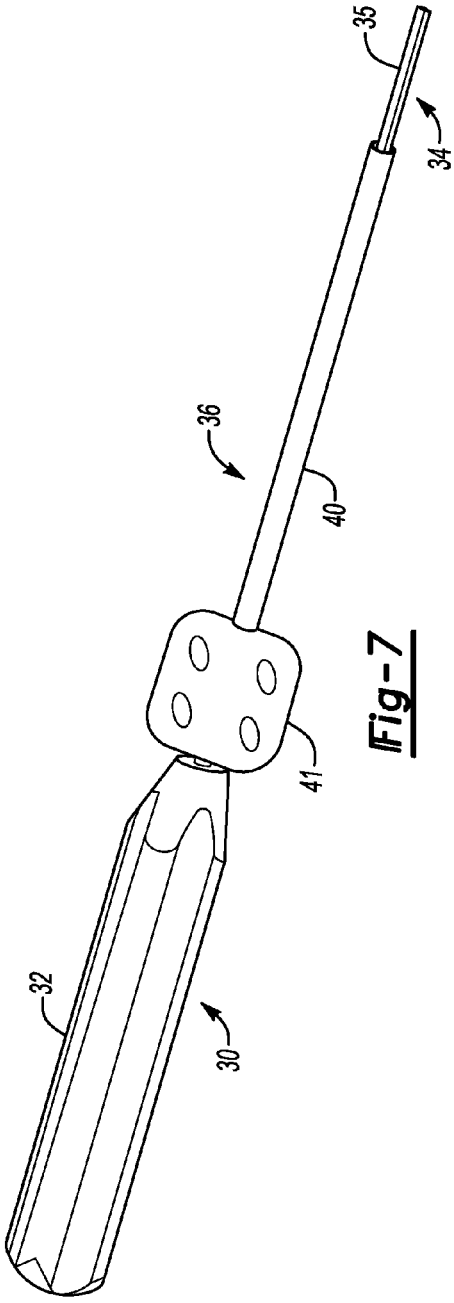

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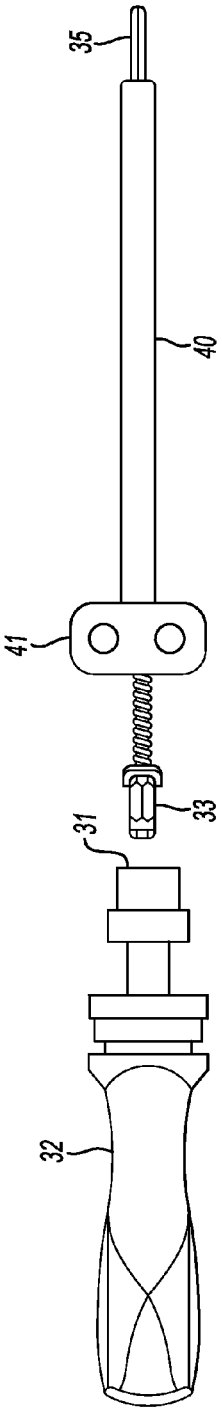

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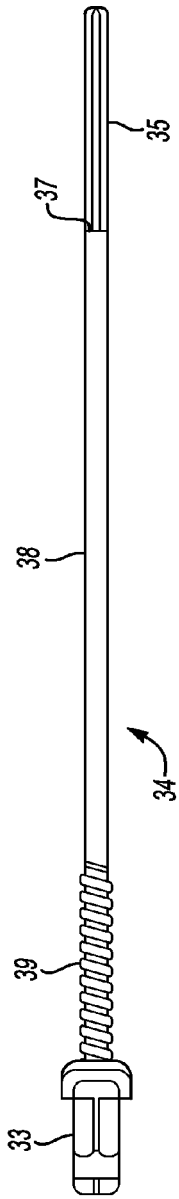

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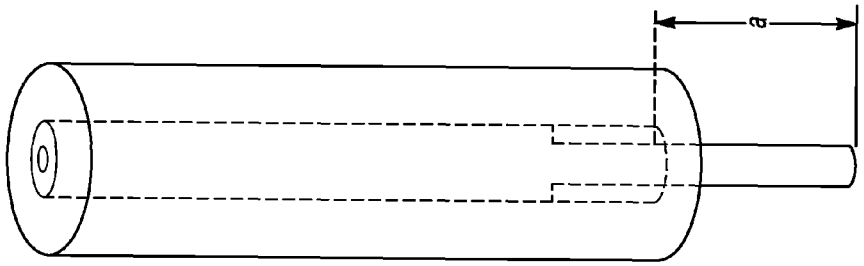

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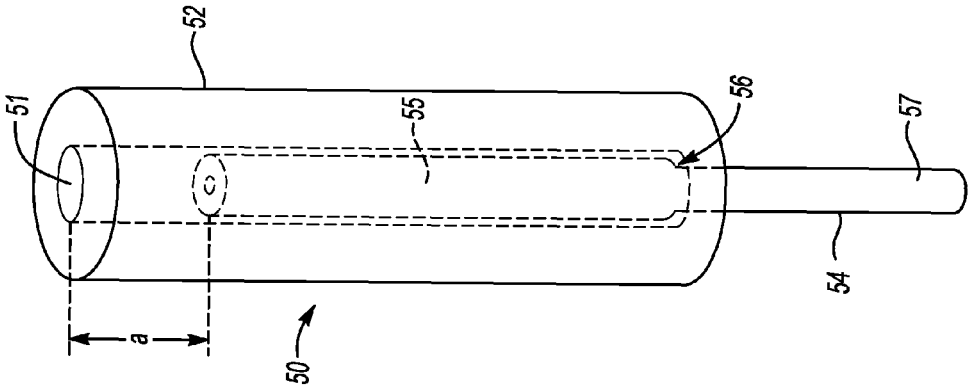

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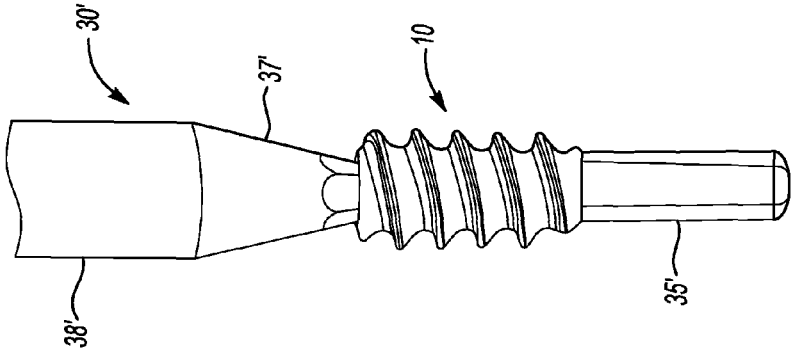

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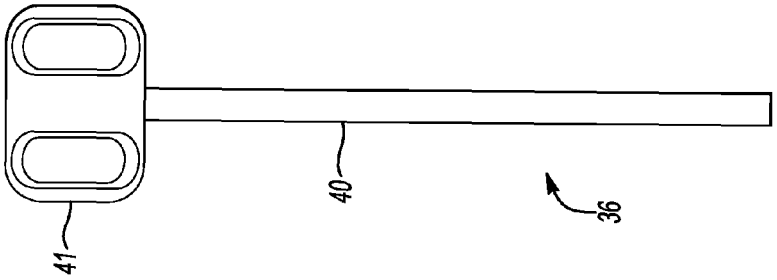

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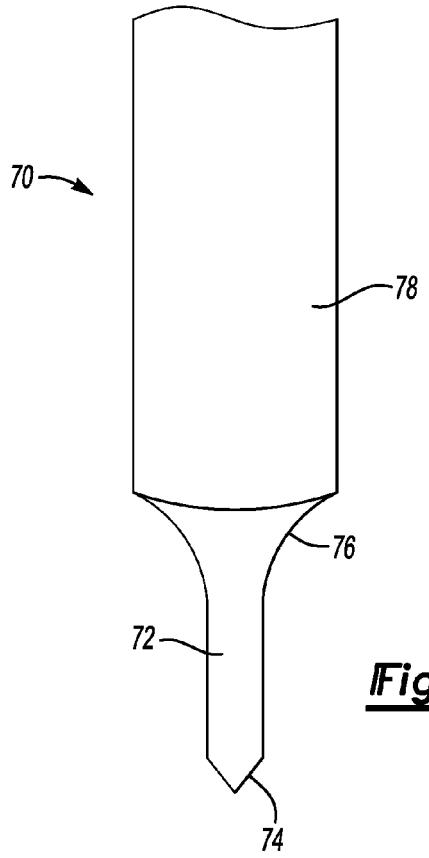

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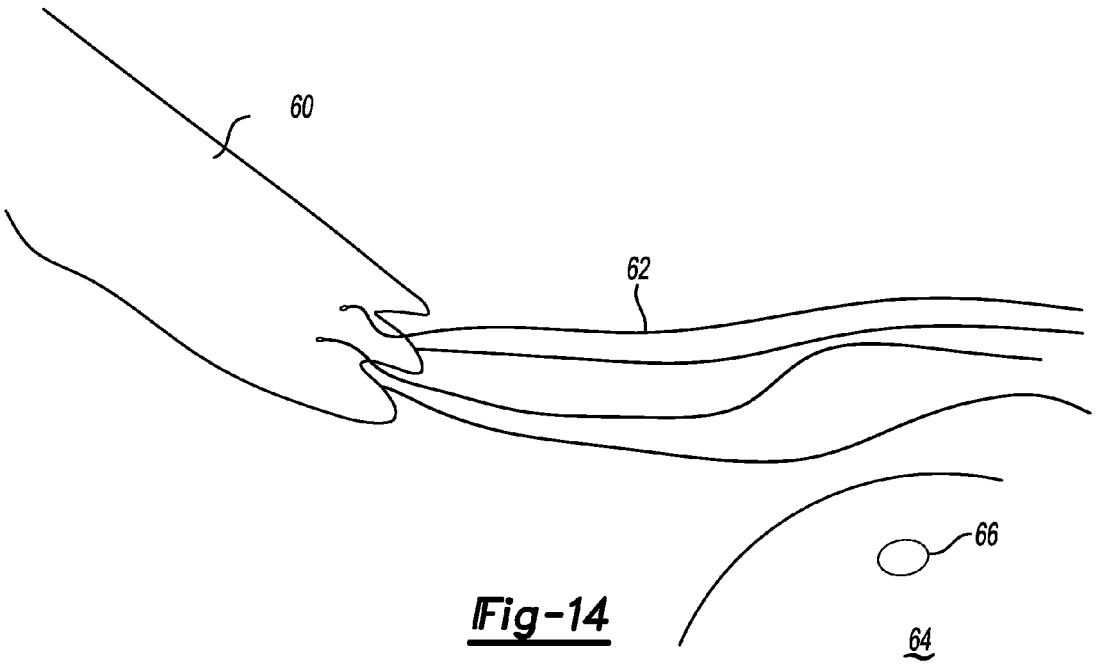

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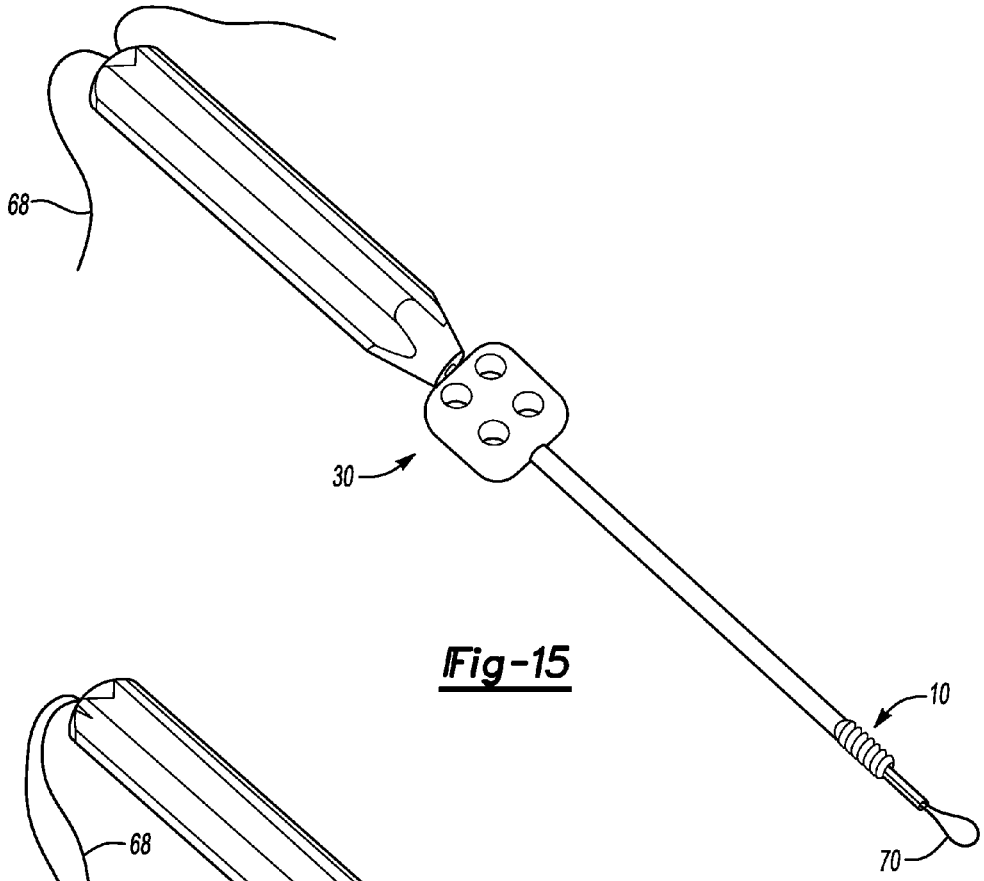

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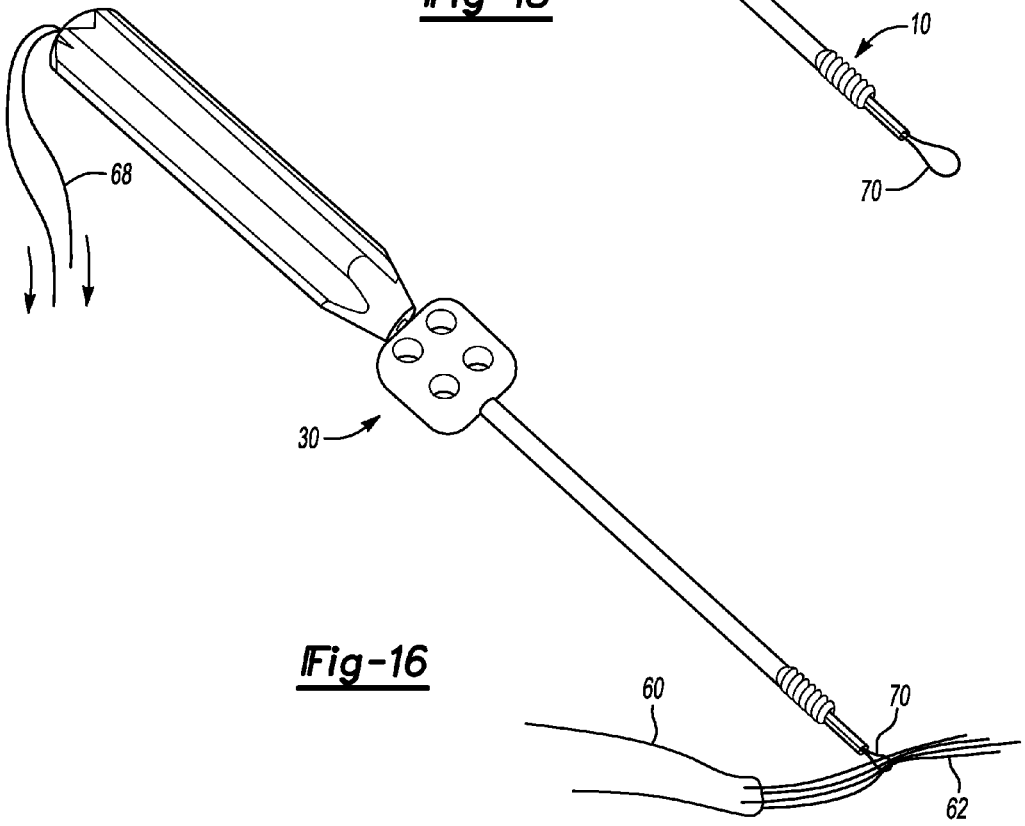

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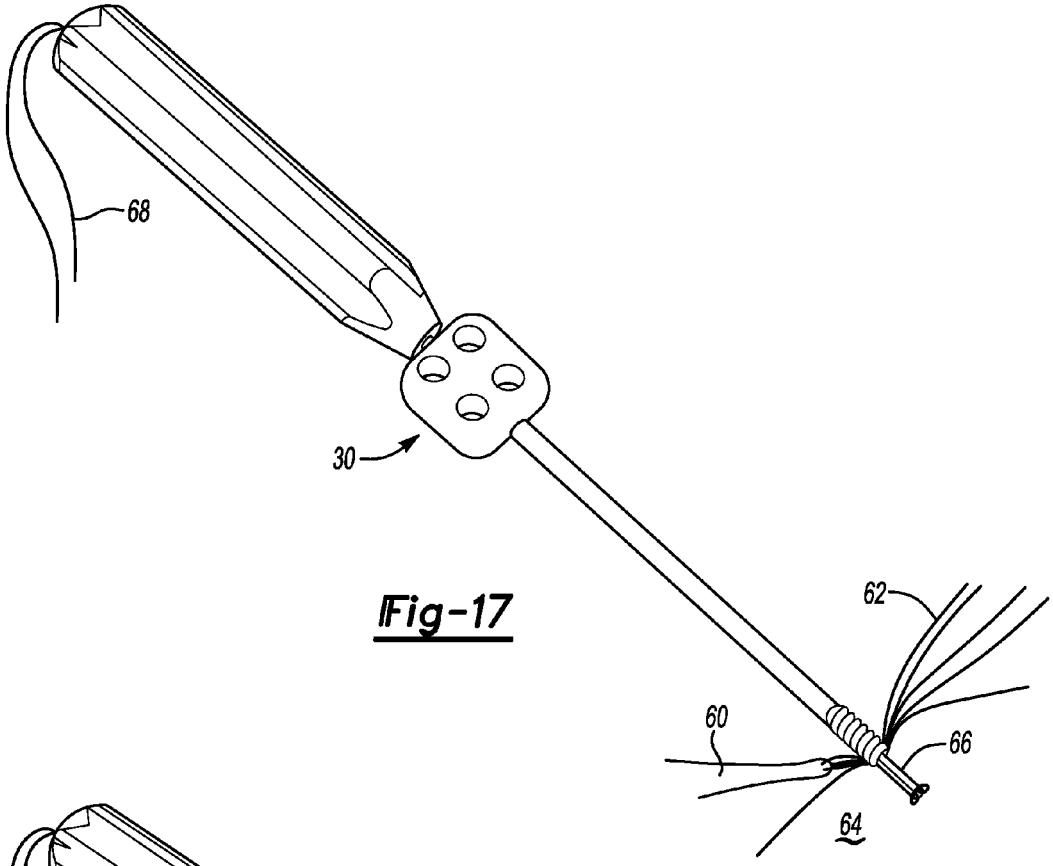

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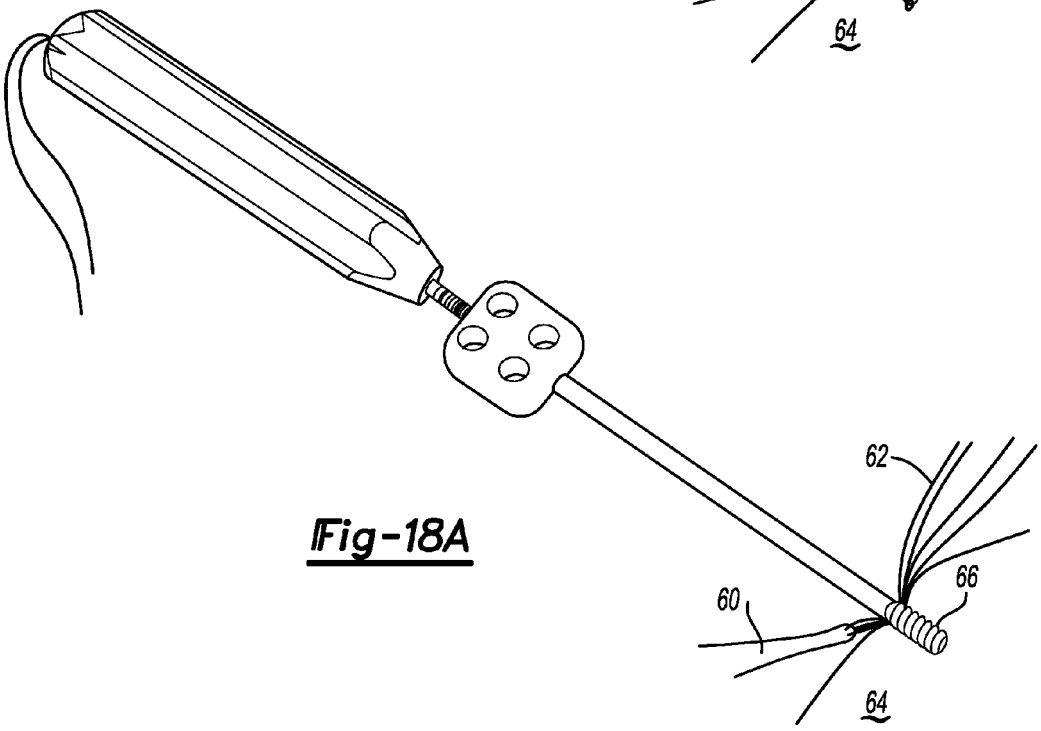

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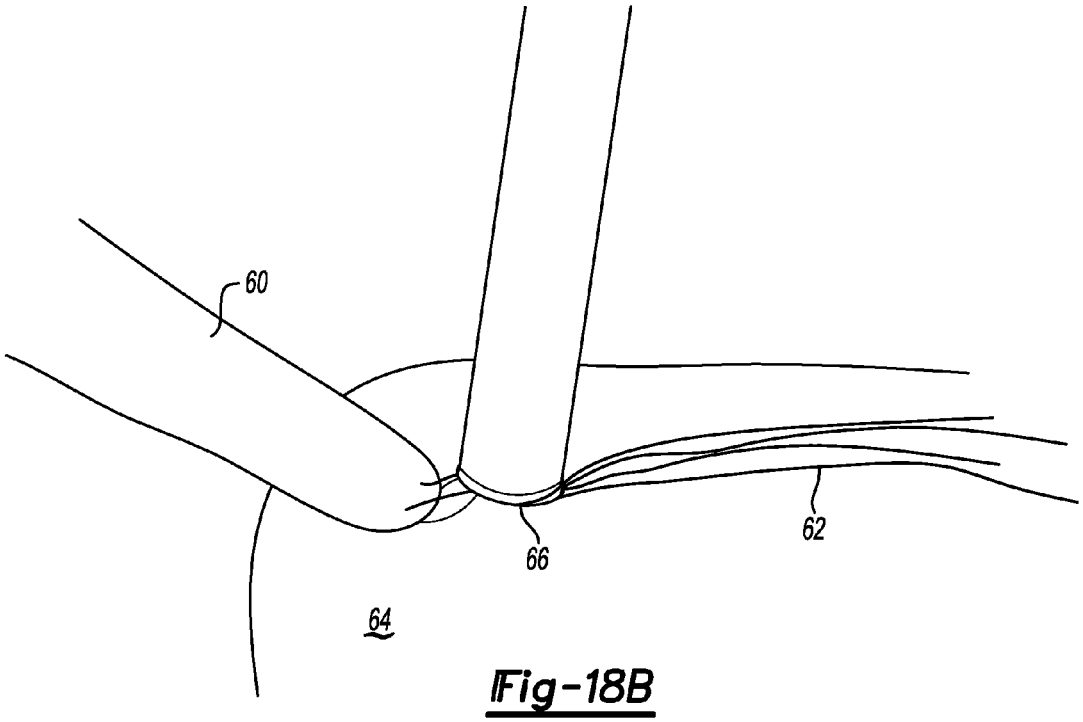

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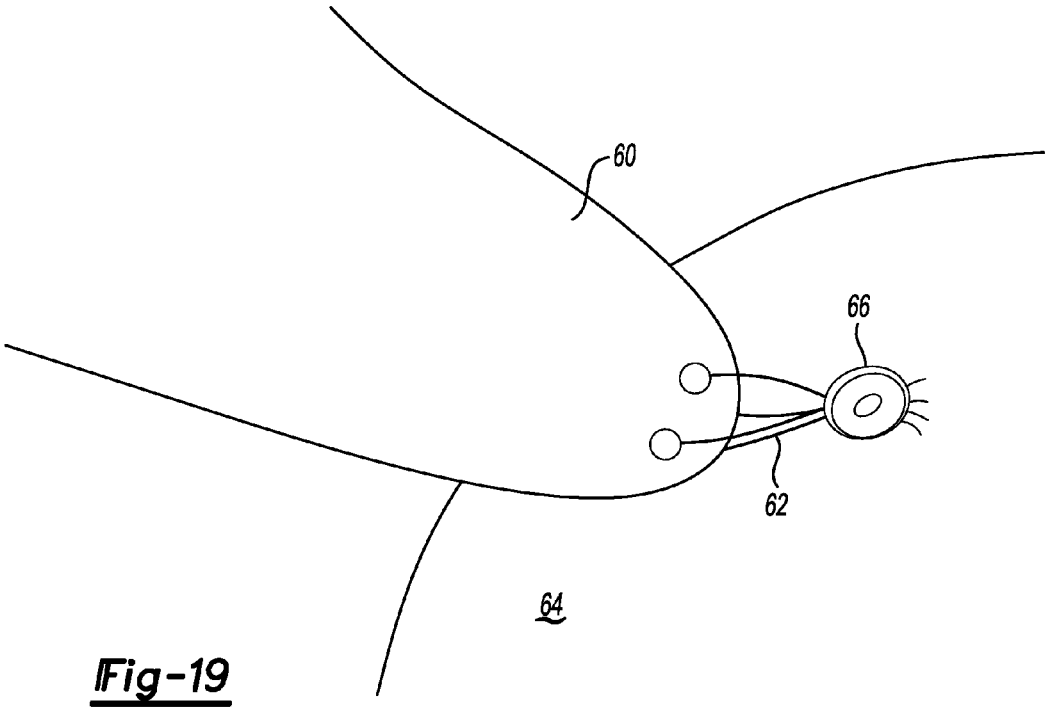

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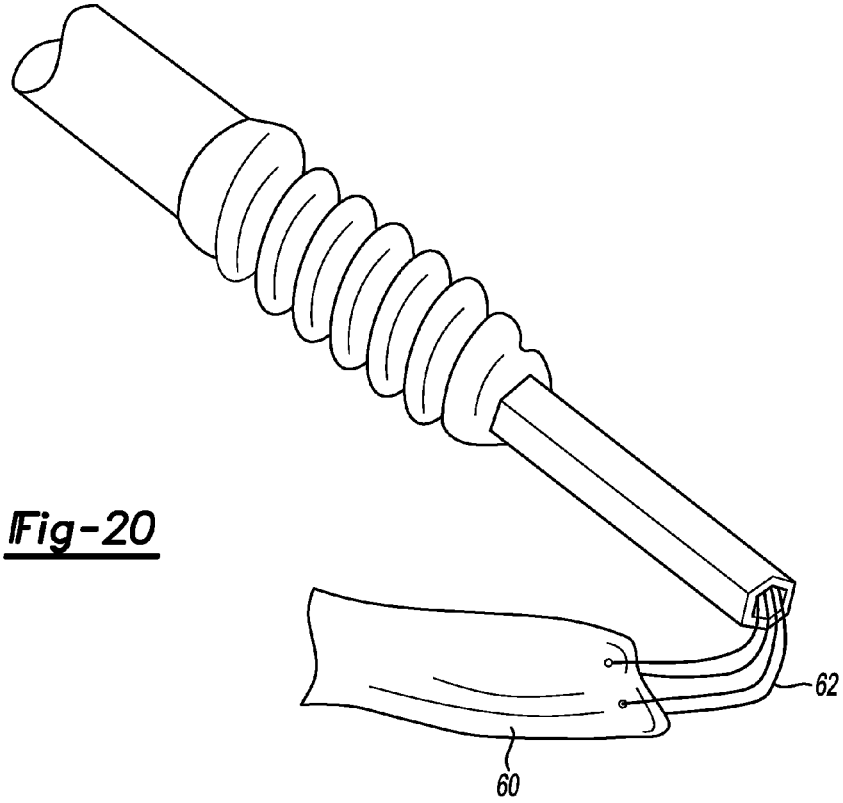

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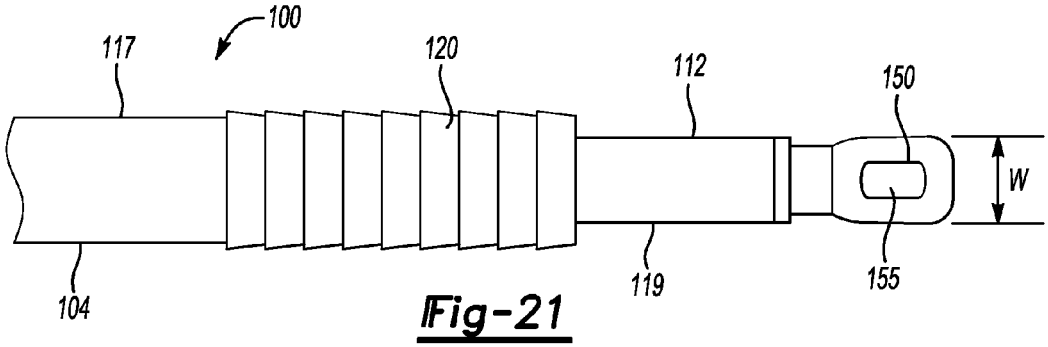

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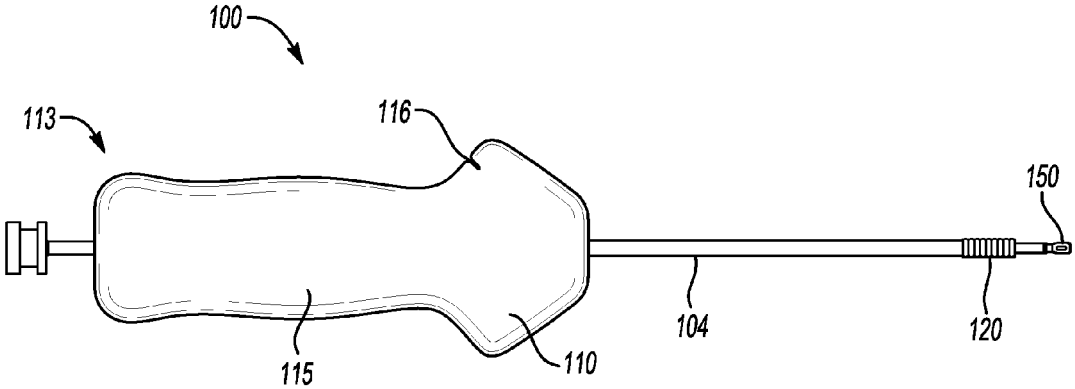

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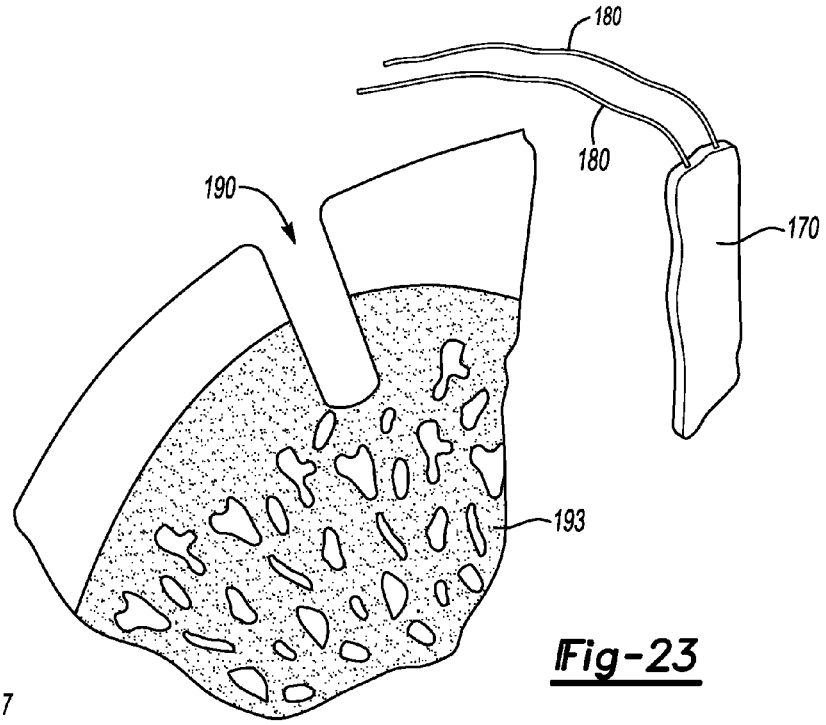
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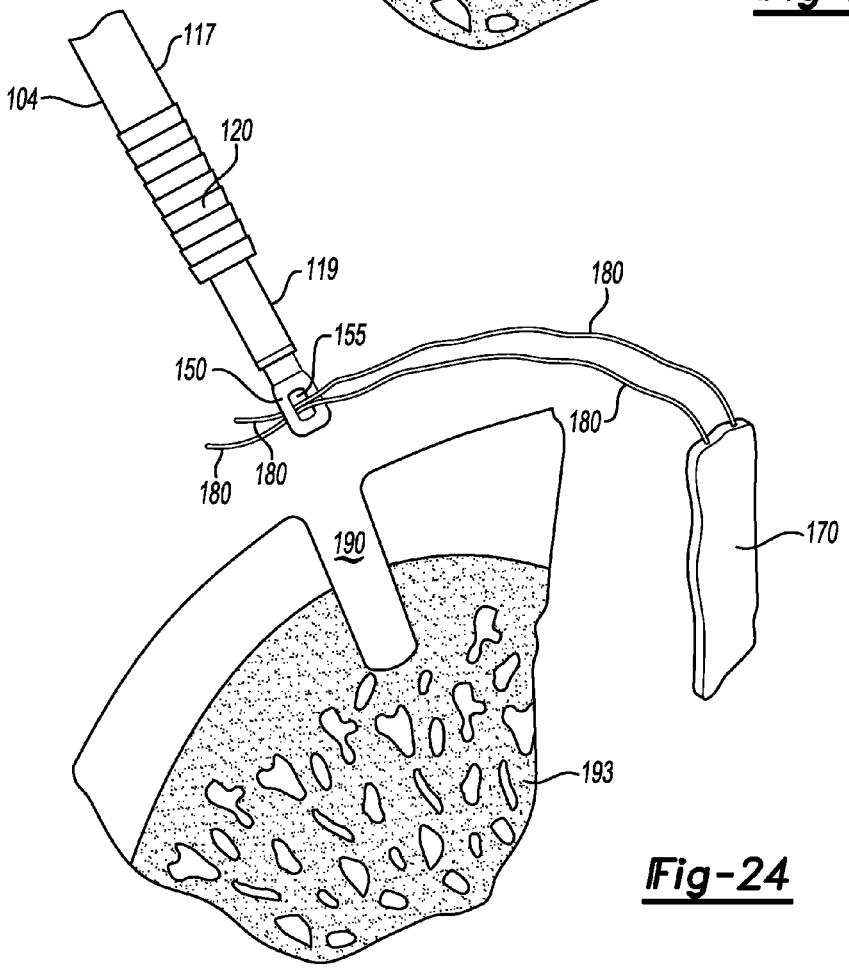
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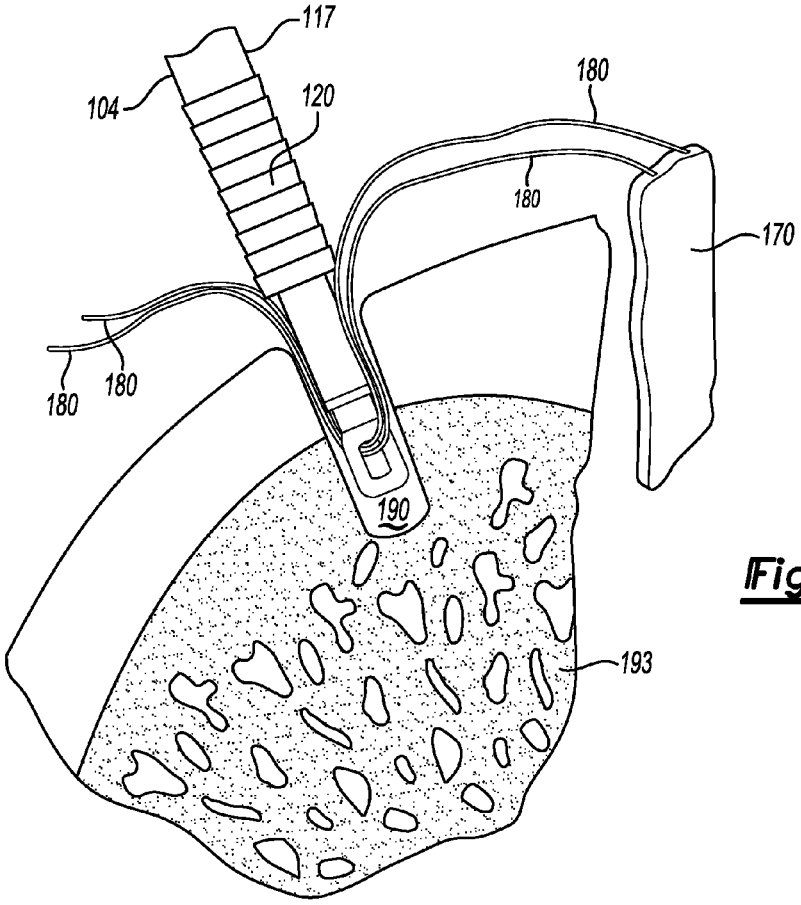
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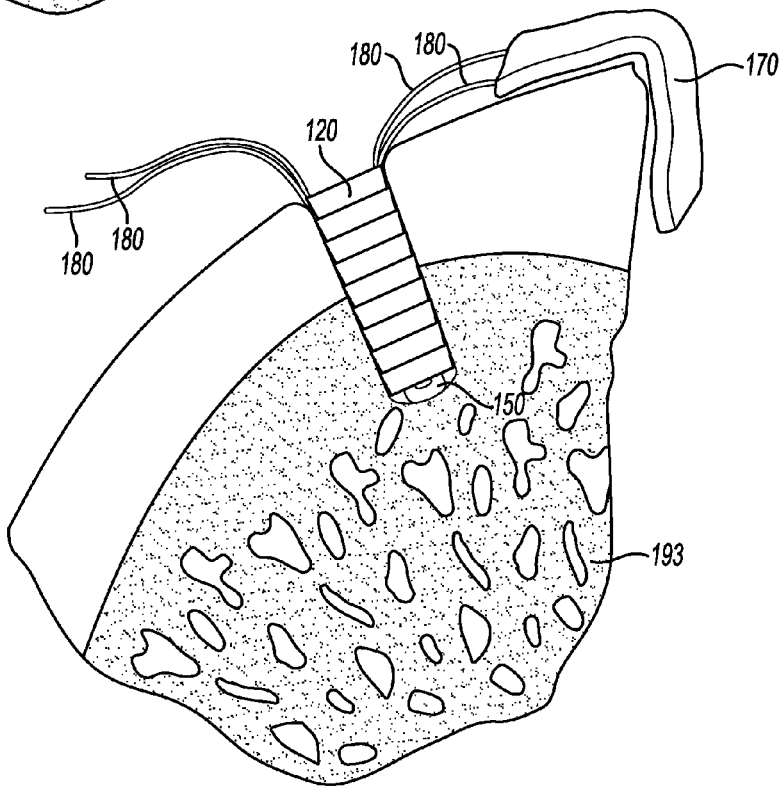
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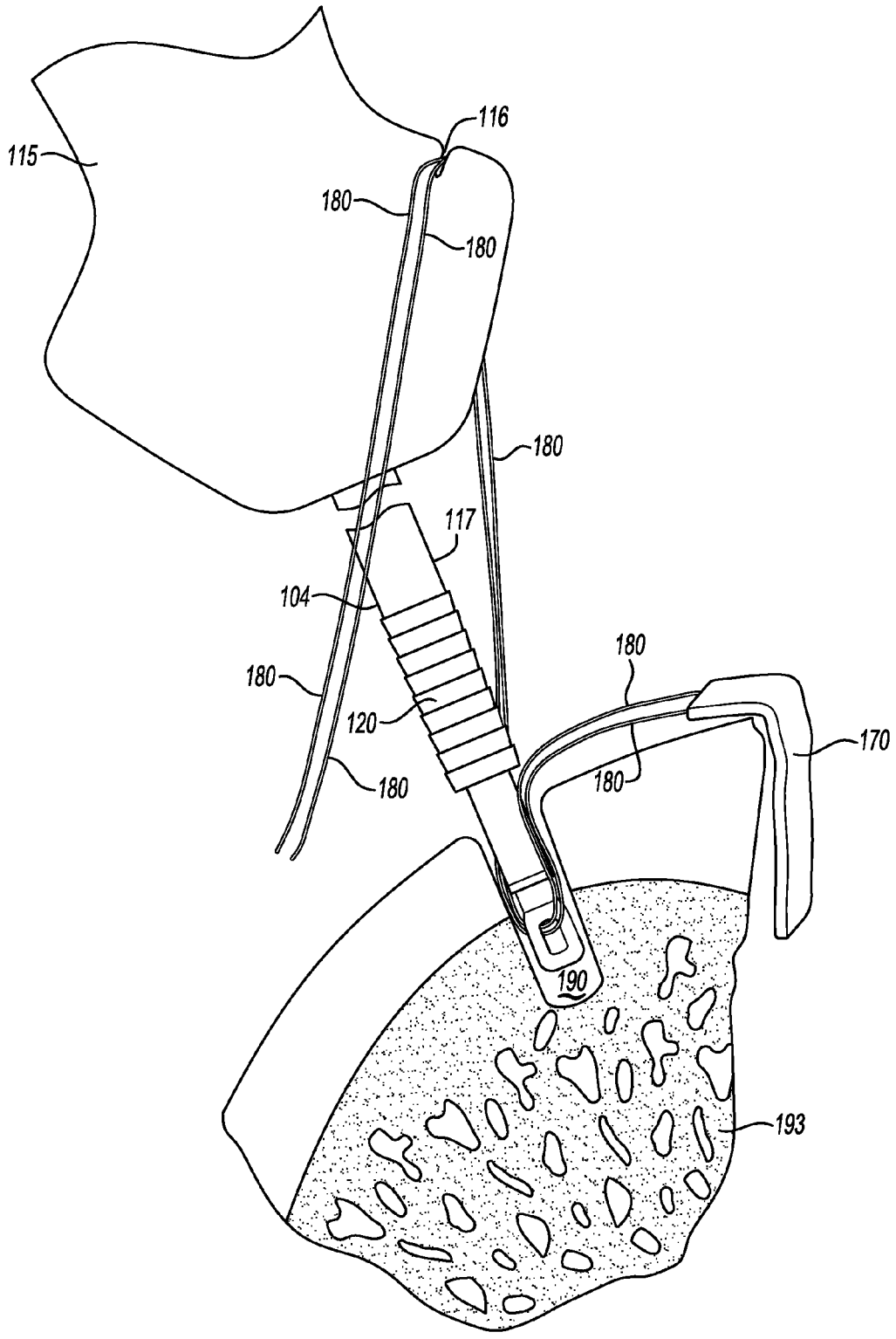

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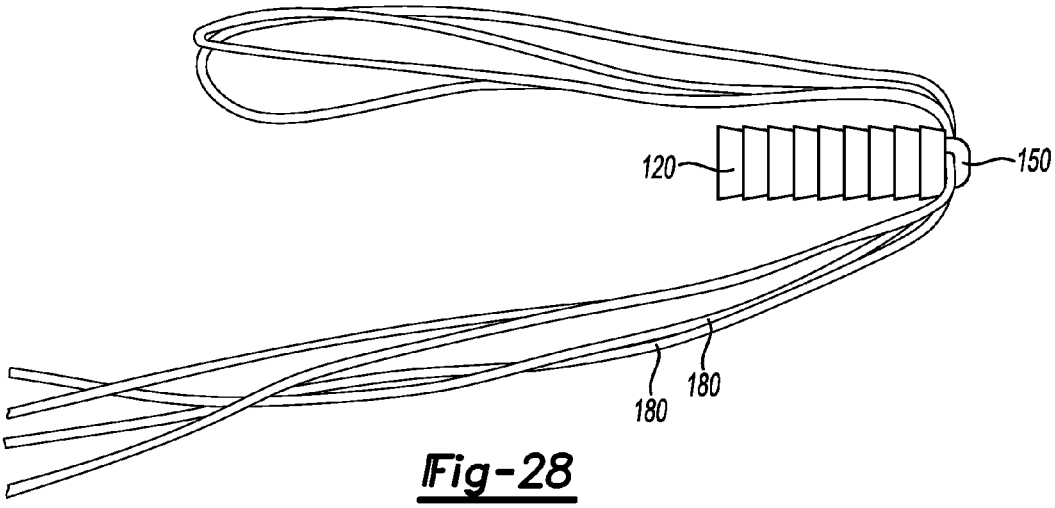

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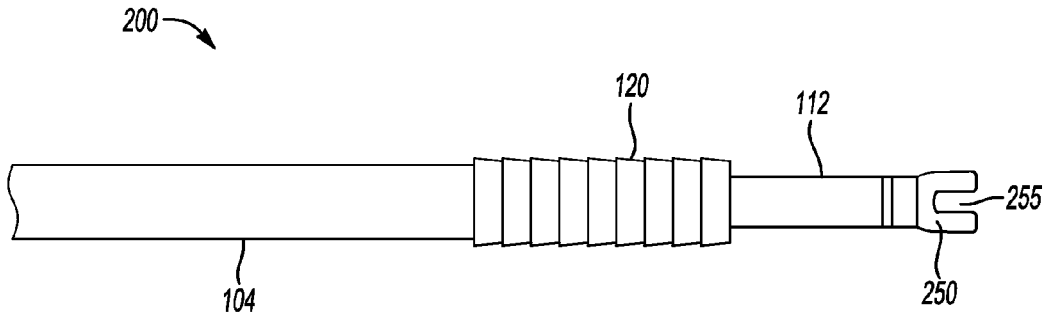

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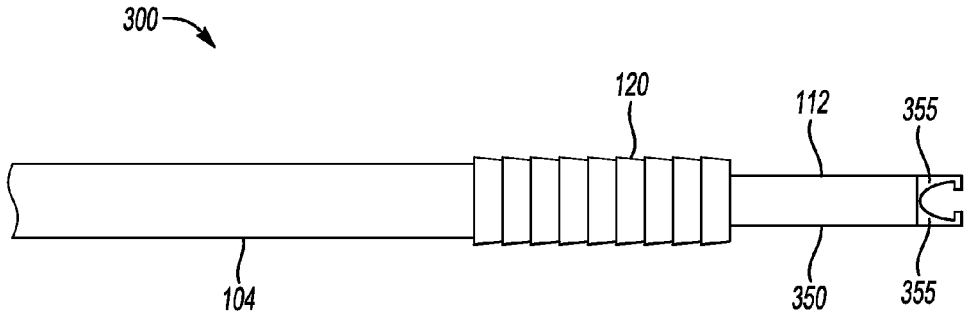

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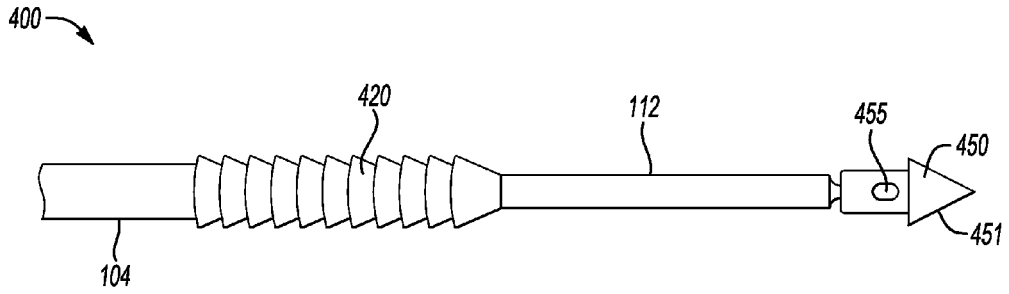

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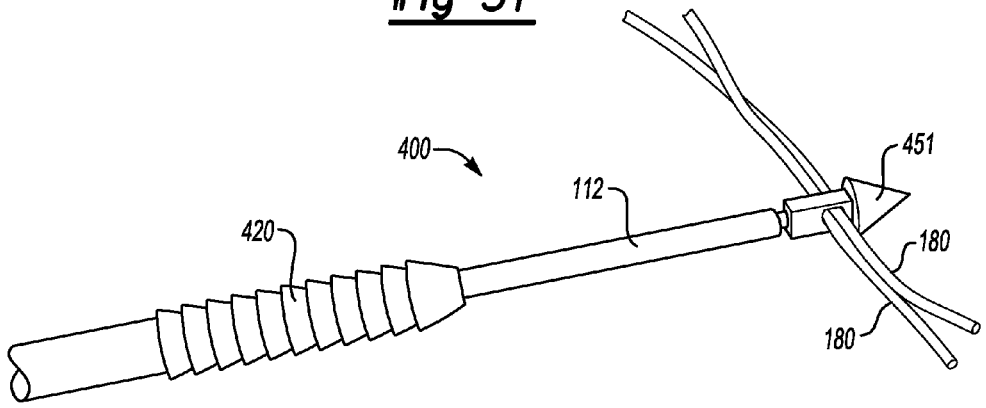

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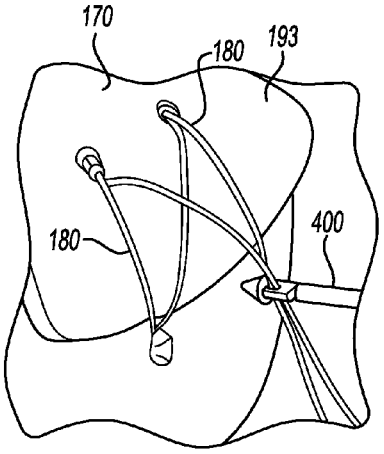

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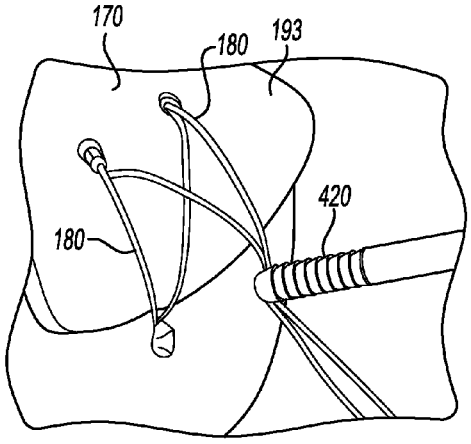

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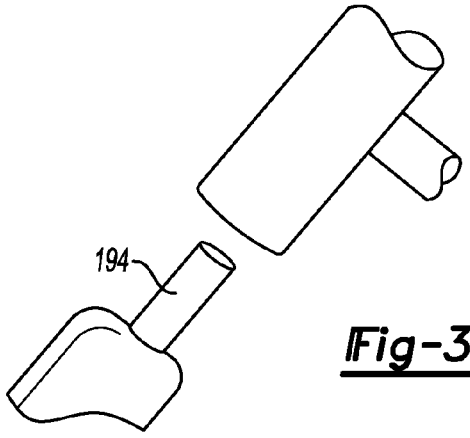

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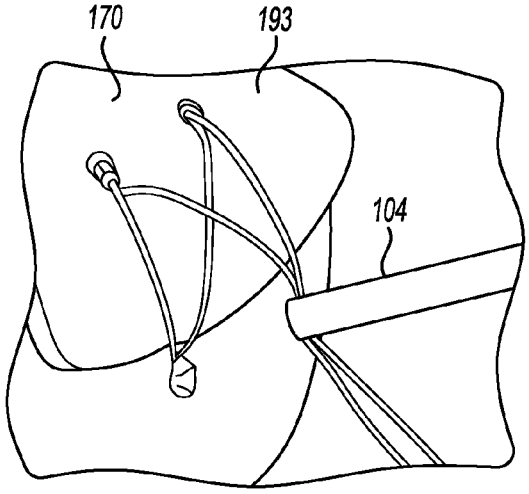

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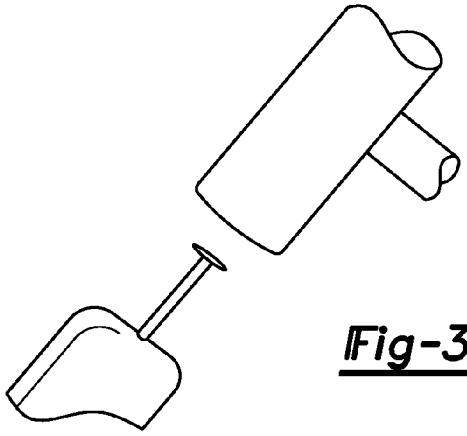

Fig-35A

KNOTLESS GRAFT FIXATION ASSEMBLY

CROSS REFERENCE TO RELATED APPLICATIONS

This is a continuation of U.S. patent application Ser. No. 13/765,218 filed Feb. 12, 2013, which is a divisional of U.S. application Ser. No. 13/182,893, filed Jul. 14, 2011, now U.S. Pat. No. 8,430,909, which is a continuation of U.S. application Ser. No. 12/022,868, filed Jan. 30, 2008, now U.S. Pat. No. 7,993,369, which is a continuation-in-part of U.S. application Ser. No. 10/405,707, filed Apr. 3, 2003, now U.S. Pat. No. 7,329,272, which is a continuation-in-part of U.S. application Ser. No. 09/886,280, filed Jun. 22, 2001, now U.S. Pat. No. 6,544,281, which claims the benefit of U.S. Provisional Application No. 60/213,263, filed Jun. 22, 2000.

BACKGROUND

When soft tissue such as a ligament or a tendon becomes detached from a bone, surgery is usually required to reattach or reconstruct the tissue. Often, a tissue graft is attached to the bone to facilitate regrowth and permanent attachment. Various fixation devices, including sutures, screws, staples, wedges, and plugs have been used in the past to secure soft tissue to bone. In typical interference screw fixation, for example, the graft is fixed to the bone by driving the screw into a blind hole or a tunnel in the bone while trapping the end of the graft between the screw and the bone tunnel. In other methods, the graft is simply pinned against the bone using staples or sutures tied around the end of the graft to the bone.

More recently, various types of threaded suture anchors have been developed. The application of such suture anchors generally requires the surgeon to tie knots in the suture to secure the tissue to the bone, which is tedious and time-consuming. The surgical procedure would be less cumbersome for the surgeon and ultimately more beneficial to the patient if the tissue could be attached to the bone without the surgeon having to tie suture knots.

SUMMARY

Illustrative embodiments disclosed below are useful for securing soft tissue to bone with excellent pull-out strength without requiring a surgeon to tie suture knots to secure the suture in place or to secure the tissue to the bone. The disclosed examples may be used to secure any type of soft tissue, graft, or tendon.

An illustrative example suture securing assembly includes an inserter having a distal end, a proximal end, and a longitudinal axis between the distal end and the proximal end. A first member includes an eyelet oriented to thread suture across the longitudinal axis. The first member is situated near the distal end of the inserter. The first member is configured to be placed in bone. A second member is situated near the distal end of the inserter. The second member is moveable relative to the first member in a distal direction toward the eyelet into a suture securing position where the second member traps suture.

Another illustrative example suture securing assembly includes a driver having a length and a width. The length is greater than the width. The length is parallel to an insertion direction. A first member is supported by the driver. The first member comprises an eyelet including an opening that is transverse to the length. The opening is configured to allow suture to be threaded through the eyelet transverse to the length. The first member is situated to be moved in the insertion direction to be received in bone. A second member is supported by the driver. The second member is situated to be moved in the insertion direction relative to at least the first member into a suture securing position where the second member traps suture.

Various features and advantages associated with disclosed embodiments of the present invention will become apparent from the following detailed description, which refers to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** illustrates a proximal end, side elevational view of an interference screw according to an embodiment of the present invention.

FIG. **2** is a proximal end view of the screw shown in FIG. **1**.

FIG. **3** is a cross-sectional view, drawn along line III-III of FIG. **2**, of the screw shown in FIG. **1**.

FIG. **4** illustrates a side elevational view of an interference plug according to an embodiment of the present invention.

FIG. **5** is a cross-sectional view of the plug shown in FIG. **4**.

FIG. **6** is a distal end view of the plug shown in FIG. **6**.

FIG. **7** illustrates a driver according to an embodiment of the present invention for driving the interference screw shown in FIG. **1**.

FIG. **8** shows a handle according to a variation of the driver seen in FIG. **7**.

FIG. **9** shows the inner shaft attachable to the driver handle shown in FIG. **8**.

FIG. **10** shows the outer shaft of the driver according to an embodiment of the present invention.

FIG. **11** illustrates an alternative embodiment of a driver and an interference screw.

FIGS. **12**A and **12**B illustrate a driver according to an embodiment of the present invention usable for the interference plug shown in FIG. **4**.

FIG. **13** illustrates a punch usable in connection with an embodiment of the present invention to create a bone socket for securing the graft.

FIG. **14** illustrates a graft to be secured to the bone with attached sutures, and a socket created in the bone at the location at which the graft is to be affixed.

FIG. **15** shows the driver of FIG. **7** loaded with an interference screw and having a traction suture loop formed near the distal end of the driver.

FIG. **16** illustrates the sutures attached to the graft being passed through the suture loop according to an embodiment of present invention.

FIG. **17** is a view through a cross-section of the bone socket which shows the sutures attached to the graft being held in contact with the bottom of the bone socket with the interference screw positioned just out of the socket.

FIG. **18**A is a view through a cross-section of the bone through the socket.

FIG. **18**B illustrates the same step of the invention as shown in FIG. **18**A, but provides a close-up view from the surgeon's perspective.

FIG. **19** shows the graft secured to the bone as a result of a method according to an embodiment of the present invention.

FIG. **20** illustrates an alternative embodiment of a method according to the present invention in which the sutures attached to the graft are threaded directly into and through the driver instead of through a suture loop at the distal end of the driver.

FIG. **21** illustrates a perspective view of a distal end of a push lock driver of an embodiment of the present invention.

FIG. **22** illustrates a perspective view of the push lock driver of FIG. **21**.

FIG. **23** is a schematic cross-sectional view of a surgical site undergoing a graft fixation technique according to a method of an embodiment of the present invention.

FIG. **24** is a schematic view of the surgical site of FIG. **23** undergoing a graft fixation technique with the push lock driver of FIGS. **21** and **22**.

FIG. **25** is a schematic view of the surgical site of FIG. **23** undergoing a graft fixation technique with the push lock driver of FIGS. **21** and **22** and at a stage subsequent to that shown in FIG. **24**.

FIG. **26** is a schematic view of the surgical site of FIG. **23** undergoing a graft fixation technique with the push lock driver of FIGS. **21** and **22** and at a stage subsequent to that shown in FIG. **25**.

FIG. **27** is a schematic view of the surgical site of FIG. **23** undergoing a graft fixation technique with the push lock driver of FIGS. **21** and **22** and at a stage subsequent to that shown in FIG. **26**.

FIG. **28** is a schematic view of an eyelet implant of an embodiment of the present invention secured by and locked into an interference device in accordance with an embodiment of the present invention.

FIG. **29** illustrates a perspective view of a distal end of a push lock driver in accordance with an embodiment of the present invention.

FIG. **30** illustrates a perspective view of a distal end of a push lock driver in accordance with another embodiment of the present invention.

FIG. **31** illustrates a perspective view of a distal end of a push lock driver in accordance with another embodiment of the present invention.

FIG. **32** illustrates another perspective view of the push lock driver of FIG. **31** with a strand passed through an aperture of the push lock.

FIG. **33** is a schematic cross-sectional view of a surgical site undergoing a graft fixation technique with the push lock driver of FIGS. **31** and **32**.

FIGS. **34** and **34**A are schematic views of the surgical site of FIG. **33** at a graft fixation stage subsequent to that shown in FIG. **33**.

FIGS. **35** and **35**A are schematic views of the surgical site of FIG. **33** at a graft fixation stage subsequent to that shown in FIGS. **34** and **34**A.

DETAILED DESCRIPTION

Referring to FIGS. **1-3**, an interference screw **10** according to an embodiment of the present invention is shown. Screw **10** is preferably formed of a bioabsorbable material such as PLLA and has a cannulated body **12** provided with a continuous thread **16** having rounded outer edges **18**. The head **14** of the screw is rounded to minimize abrasion or cutting of tissue, and the screw tapers toward the distal end. A hexagonal bore **15** formed through the screw accepts a driver shaft described in more detail below.

FIGS. **4-6** illustrate an interference plug **20** according to an alternative embodiment of the present invention. Plug **20** is also preferably formed of a bioabsorbable material and has a cannulated body **22** provided with rounded annular ribs **24** separated by rounded annular grooves **26**. The outer diameter of the ribs and grooves is substantially constant. The plug tapers significantly toward the distal end. Cannula **28** is preferably round in cross-section but may also be hexagonal or any other shape, and is designed to accommodate the shaft of a corresponding driver.

FIG. **7** illustrates a driver **30** according to an embodiment of the present invention for driving the interference screw described above. Generally, driver **30** includes a handle **32**, inner shaft **34**, and outer shaft **36**. FIG. **8** shows a handle having a connector **31** for coupling with driver **30**.

FIG. **9** shows the inner shaft of driver **30**. Inner shaft **34** has a cannula extending through its entire length and has openings at the proximal and distal ends to enable sutures to be passed therethrough. Inner shaft **34** includes a shaft body **38** having a threaded proximal section **39** and a hex-shaped distal section **35** for being fitted through the cannula **15** in interference screw **10**. The diameter of the shaft body **38** is reduced slightly along the hex section **35**, forming a shoulder **37** at the junction between the hex section **35** and the central portion of shaft body **38** for abutting the proximal end of an interference screw loaded onto the driver. Shaft **34** can be permanently affixed to the handle **32** as shown in FIG. **7**, or can be releasably attached, as shown in the embodiment represented in FIGS. **8** and **9**, by means of a collet **33** at the proximal end of the threaded section **39** being fittable within a connector **31** at the distal end of handle **32**.

FIG. **10** shows the outer shaft **36** of the driver **30**. Outer shaft **36** includes a sleeve **40** which covers and is slidable over shaft body **38**, and a thumb pad **41** for being gripped by a user. Outer shaft **36** is cannulated through its entire length, of course, with the diameter of the cannula being slightly larger than the outer diameter of the central portion of inner shaft body **38**. The portion of the cannula through thumb pad **41** is threaded to mate with the threads on the threaded proximal section **39** on inner shaft **34**. The inner diameter of the inner threads in thumb pad **41** is smaller than the outer diameter of the central portion of shaft body **38**, so as to limit the proximal movement of the outer shaft **36** relative to the inner shaft **34**.

The proximal threaded section **39** on the inner shaft **34** has a length such that when the outer shaft **36** is unscrewed to its proximal-most position with the thumbpad adjacent the distal end of handle **32** or connector **31**, shoulder **37** on the inner shaft **34** is flush with or exposed through the distal end of sleeve **40** of outer shaft **36**.

The length of hex section **35** is such that when a cannulated interference screw is loaded onto the driver with the proximal end of the screw abutting the shoulder **37**, the hex driver portion exposed distally of the mounted screw can reach the bottom of a socket created in the bone where the screw will be inserted, while the screw is positioned just outside the hole. Thus, the hex section **35** has a length which is approximately twice the length of the interference screw usable with the driver. Similarly, the length of the threaded proximal section **39** is also approximately equal to the length of the screw.

An alternative embodiment of the driver for the interference screw is shown in FIG. **11**. In this embodiment, the outer shaft is eliminated so that the driver **30'** is comprised of a single cannulated shaft. The shaft body **38'** has an enlarged outer diameter relative to that of the previous embodiment, and tapers down to hex section **35'** via a tapered section **37'**. When loading a screw onto the driver **30'**, the proper initial position of the screw is established by inserting the hex section through the cannula of the screw until the travel of the proximal end of the screw **10** is limited by the increased diameter in tapered section **37'**. As before, the hex section has a length which enables the distal end of the hex section to be inserted to the bottom of the socket while positioning an intereference screw loaded onto the driver just outside the

socket with the bottom thread of the screw able to engage the opening of the hole upon the application of a small amount of force into the hole.

FIGS. **12**A and **12**B illustrate an example of a driver usable with an interference plug in accordance with an embodiment of the present invention, in which the plug is driven into the socket by impaction rather than being screwed into place. Driver **50** comprises essentially of an outer shaft **52** and a cannulated inner shaft **54**. Inner shaft **54** is inserted into the cannula **51** of outer shaft **52** and has a proximal portion **55** which has an outer diameter slightly smaller than the diameter of cannula **51** to enable the outer shaft **52** to slide along proximal portion **55**. Inner shaft **54** also has a distal portion **57** which has a diameter smaller than that of proximal portion **55** and sized for insertion into the cannula **28** of interference plug **20**. The cross-sectional shape of distal portion **57**, and hence of cannula **28** of plug **20**, is preferably round, but can also be hex or any other shape, as long as the distal portion **57** of inner shaft **54** is matingly shaped with the distal portion **57** of driver **50** to be insertable into cannula **28** of plug **20**. The junction between proximal portion **55** and distal portion **57** forms shoulder **56** for abutting the proximal end of the plug when the plug is loaded onto the driver **50**.

The length of outer shaft **52** is equal to the length of proximal portion **55** of inner shaft **54** plus a distance "a" equal to the length of the interference plug usable therewith. The length of distal section **57** is approximately equal to twice the length of a plug **20**, and shoulder **56** on the inner shaft **54** is flush with or just exposed through the distal end of outer shaft **52** when outer shaft **52** is in its fully retracted (proximal) position.

A method of performing soft tissue fixation in accordance with an embodiment of the present invention will now be described with reference to FIGS. **14**-**19**.

As shown in FIG. **14**, sutures **62** are passed through the graft **60** at desired points, and a blind hole or socket **66** is created in the bone **64**, using a drill or punch, at the location where the tissue is to be secured. A punch provides the advantages of rounding the opening edge of the bone socket to protect the sutures attached to the graft from being sheared during the insertion process, and also compacts the bone at the punch site for better purchase of the bone by the anchor in cases where the bone is a soft bone. An example of such a punch is illustrated in FIG. **13**, the punch having a constant diameter section **72**, a tip **74**, a flared section **76**, and a main body portion **78**. The diameter of the constant diameter section corresponds to the diameter of the driver.

Next, as shown in FIG. **15**, driver **30** is pre-loaded with screw **10** with outer shaft **36** in the fully retracted position and the distal end of the screw abutting shoulder **37** of inner shaft **34** and the distal end surface of outer shaft **36**. Traction suture **68** is passed into the cannula of the driver, such that a looped end **70** is exposed at the distal end of the driver. Sutures **62** attached to graft **60** are then passed through traction suture loop **70** at the end of driver **30** as seen in FIG. **16**, to position the graft at an appropriate distance from the distal end of driver **30**, either at a distance corresponding to the length of the screw or so that the graft is located directly at the distal end of the driver.

Referring now to FIG. **17**, the driver **30** is held with gentle pressure with the distal end of hex section **35** at the bottom of the hole **66**, keeping the screw **10** just outside the hole. Tension can then be placed on the graft sutures **62** by drawing on traction suture **68** to tighten suture loop **70**. Once adequate tension is achieved on the sutures, the driver is manipulated so that the first thread edge of the screw engages the bone at the edge of the hole **66**. The driver is turned by rotating handle **32** and thus inner shaft **34** while preventing outer shaft **36** from rotating by holding thumb pad **41** in place during rotation of handle **32**. This maneuver causes the outer shaft to move distally along the inner shaft by the interaction of the inner threads in the outer shaft **62** with the threads on threaded portion **39** of inner shaft **34**, while also causing the screw threads to engage the sides of the hole and pull the screw into the hole. The inner shaft of the driver thus rotates without advancing further into the hole, while the outer shaft guides the insertion of the screw into the socket. In this manner, the screw advances along the hex section of the driver until the screw is fully installed to the position shown in FIGS. **18**A and **18**B, with sutures **62** or the graft **60** pinned and/or wound between the base and sidewall of socket **66** and interference screw **10**. Optionally, sutures **62** may be twisted together at the time they are passed through loop **70** to increase contact with the screw upon insertion of the screw into the socket.

After the screw is fully inserted, traction loop **70** is disengaged from the handle, and the driver is removed. As seen in FIG. **19**, the ends of the sutures can be removed by clipping them short, leaving the graft securely fastened in place to the bone.

A procedure similar to that just described is performed with respect to the installation of an interference plug, except that a driver such as driver **50** shown in FIGS. **12**A and **12**B is used instead of driver **30** of FIGS. **7**-**10**, and the plug is advanced into the hole using impact force supplied by a mallet, for example, rather than by turning. When the proximal end of outer shaft **52** is hit with the mallet, the proximal end of plug **20** abutting against shoulder **56** on the inner shaft **54** and the distal surface of outer shaft **52** pushes the plug into the socket **66**. In this method, the plug is fully inserted into the hole when the proximal end of outer shaft **52** is flush with the proximal end of inner shaft **54**.

In a first alternative to the method described above, sutures **62** attached to the graft **60** are eliminated, so that in the step shown in FIG. **16**, the graft itself is passed through the suture loop **70** to be secured from the bottom of the hole **66** by the tip of plug **20**.

In an alternative to the method described above, traction suture **68** and loop **70** are eliminated, so that in the step shown in FIG. **16**, instead of passing sutures **62** through loop **70**, the ends of sutures **62** are threaded into the cannula of the inner shaft **34** through the distal end thereof, through the length of driver **30** or **50**, and out the opening at the proximal end thereof, as illustrated in FIG. **20**.

FIGS. **21** and **22** illustrate an implant driver **100** of another embodiment of the present invention. Driver **100** includes a body **104**, preferably in the form of a cylinder, and having a distal end **112** (FIG. **21**) and a proximal end **113** (FIG. **22**). The body **104** of driver **100** includes an outer shaft **117** and an inner shaft **119**. The outer shaft **117** is cannulated for receiving inner shaft **119**.

As illustrated in FIG. **21**, driver **100** is pre-loaded with an interference device **120**. Preferably, the interference device **120** is a screw or an interference plug, preferably formed of a bioabsorbable material such as PLLA. If a screw is employed, the screw may be provided with a cannulated body provided with a continuous thread having rounded outer edges. The head of the screw may be rounded to minimize abrasion or cutting of tissue. The cannulation formed through the screw is preferably hex-shaped and accepts the correspondingly shaped inner shaft **119** of driver **100**. If an interference plug is desired, the plug is provided with rounded annular ribs separated by rounded annular grooves. The outer diameter of the ribs and grooves is substantially constant. The plug tapers significantly toward the distal end. The plug also comprises a

cannula, preferably hex-shaped, for accommodating the inner correspondingly shaped shaft **119** of the corresponding driver **100**.

As also shown in FIG. **21**, an eyelet implant **150** is provided at the distal end **112** of driver **100**. The eyelet implant **150** is releasably attached to the distal end **112** of driver **100** by means of a connector **157**. The eyelet implant **150** is formed of a transparent polymer material, and is preferably made of a bioabsorbable material such as PLLA, polyglycolic or polylactic acid polymers. Advantageously, the eyelet implant **150** is made of a material similar to that of the interference device **120**. As illustrated in FIG. **21**, the eyelet implant **150** is provided with aperture **155** for receiving a suture attached to a graft to pass through the eyelet implant **150**, as described in more detail below. The width "w" (FIG. **21**) of the eyelet implant **150** is about equal the diameter of the inner shaft **119** and slightly smaller than the diameter of the outer shaft **117** and of the cannula of the interference device **120**.

FIG. **22** illustrates proximal end **113** of driver **100**, showing a handle **115** disposed coaxially with the body **104** and outer shaft **117** and provided with handle slots or protuberances **116**. As described below, handle slots or protuberances **116** allow a suture strand to be wrapped around the handle **115** and be subsequently tensioned prior to the impaction of the interference device **120** into the pilot hole. In this manner, the graft is precisely positioned at an appropriate distance from the pilot hole, and the suture with the attached graft is secured at the bottom of the pilot hole and prevented from exiting the pilot hole.

A method of a graft fixation technique according to an embodiment of the present invention is now described with reference to FIGS. **23-28**. The present invention may be used to secure any type of soft tissue, graft, or tendon, such as, for example, a biceps tendon or a rotator cuff. FIG. **23** illustrates at least one suture **180** passed though the graft **170** at desired points. FIG. **23** also illustrates a pilot hole or socket **190** formed in the bone or cartilage **193** using a drill or punch, at the location where the tissue is to be secured. A punch provides the advantages of rounding the opening edge of the bone socket to protect the sutures **180** attached to the graft **170** from being sheared during the insertion process, and also compacts the bone at the punch site for better attachment of the bone by the anchor in cases where the bone is a soft bone.

Next, as shown in FIG. **24**, driver **100** with a pre-loaded interference device **120** and with the outer shaft **117** in the retracted position is provided in the proximity of the bone socket **190**. Sutures **180** attached to the graft **170** are subsequently passed through the aperture **155** of the eyelet implant **150** at the end of driver **100**, as shown in FIG. **24**.

Referring now to FIG. **25**, driver **100** is held with gentle pressure so that the eyelet implant **150** at the distal end **112** is held at the bottom of the hole **190**, keeping the interference device **120** just outside the pilot hole **190**. Tension is then applied to the suture **180** by wrapping the suture **180** around the slots **116** of the handle **115** and tensioning it, as shown in FIGS. **26-27**. The suture **180** freely slides through aperture **155** of the eyelet implant **150**, allowing the graft **170** to be positioned close to the edge of the pilot hole **190**. Once tensioning of the suture **180** has been completed, the interference device **120** is then impacted into the pilot hole **190** so that the interference device **120** advances toward the distal end **112** of driver **100** and securely engages and locks in the eyelet implant **150** with the sutures **180**, as shown in FIGS. **27-28**. After the interference device **120** is fully inserted, the driver is removed and the ends of the sutures can be removed by clipping them short, leaving the graft **170** securely fastened to bone **193**.

A significant advantage of the present invention is that the sutures attached to the graft or the graft itself can be securely attached to the bone without the need to tie knots. Additionally, the suture attached to the graft is secured both by the eyelet implant and by the interference device, along the bottom and sidewalls of the pilot hole between the bone and the screw or plug, conferring a much stronger fixation of the graft to the bone than is achievable with prior art procedures and devices. More importantly, the suture attached to the graft is allowed to freely slide though the aperture of the eyelet implant to allow precise advancement and guiding of the plug or screw into the blind hole or socket during the procedure.

In another embodiment of the present invention illustrated in FIG. **29**, driver **200** is provided with a horseshoe-shaped implant **250** (i.e., an implant with an open distal end) at the distal end of the driver in lieu of the eyelet implant. The horseshoe-shaped implant **250** is provided in the form of a wedge **255** that allows the suture attached to a graft to be securely contained within the wedge, yet be capable to freely slide within the wedge. The horseshoe-shaped implant **250** is formed of a transparent polymer material, and is preferably made of a bioabsorbable material such as PLLA, polyglycolic or polylactic acid polymers. Advantageously, the horseshoe-shaped implant **250** is made of a material similar to that of the interference device **20**.

The horseshoe-shaped implant **250** may be detachable from the distal end **112** of the driver **200**, similar to the eyelet implant described in detail above. In this embodiment, the detachable horseshoe-shaped implant **250** is securely engaged within the cannulated ribbed body of the interference plug or screw **120**. Alternatively, the horseshoe-shaped implant **250** may be integral with the distal end **112** of the driver **200** and, after the interference screw or plug **120** is fully inserted into the pilot hole, the horseshoe-shaped implant **250** is removed from the site together with the driver **200**.

In yet another embodiment of the present invention and as illustrated in FIG. **30**, driver **300** of the present invention is provided with a metal tubing **350** at the distal end of a driver, which in turn, is provided with a cut or pair of protuberances **355** at its most distal end to allow at least one end of a suture attached to a graft to be securely contained within the cut, yet be capable to freely slide within the cut. Preferably, the metal tubing **350** is integral with the distal end **112** of the driver **300** and, subsequent to the full insertion of the interference screw or plug **120** into the pilot hole, the metal tubing **350** is removed from the site together with the driver **300**.

FIGS. **31-35** illustrate another embodiment of the present invention, according to which driver **400** is provided with a pointed tip implant **450** at the distal end of the driver, which is also an eyelet implant but which, because of its pointed tip, does not require the pre-drilling or pre-formation of a hole for fixating the device (implant with suture attached to graft) in the bone. The conical configuration of the most distal end of the pointed tip implant **450** allows the driver **400** with the attached implant to undergo a self-punching operation during graft fixation, eliminating any need to pre-drill a hole in the bone and providing increased fixation of the overall operation of securing the soft tissue. The conical configuration of the most distal end of the pointed tip implant **450** also provides suture fixation strength, as well as accelerated graft/tendon healing to bone. The pointed tip implant **450** may be detachable from the driver.

As illustrated in FIGS. **31** and **32**, pointed tip implant **450** is provided with an eyelet or aperture **455** for receiving at least one strand (for example, a suture strand) attached to a graft to pass through the eyelet implant **450**. Pointed tip implant **450** is also provided, at its most distal end, with a conical portion

451 which allows direct advancement of the implant (by simply tapping the device with a mallet, for example) without the formation of a bone hole. Preferably, the conical portion 451 of the implant is formed of titanium or titanium alloy. In a preferred embodiment, eyelet or aperture 455 is also formed of titanium or similar material, to withstand impaction forces during the graft fixation procedure.

As in one of the previously-described embodiments, strand 180 (attached to graft 170) is passed through the aperture 455 of the implant 450 at the end of the driver 400, as shown in FIGS. 31 and 32. Although FIG. 32 illustrate two strands 80 (i.e., two suture strands 180) passed through the aperture 455, the invention is not limited to this exemplary embodiment and contemplates additional embodiments wherein one strand or any number of strands are passed through the aperture 455. Preferably, at least one of the strands is formed of a high strength suture material such as FIBREWIRE® suture, sold by Arthrex, Inc. of Naples, Fla., and described in U.S. Pat. No. 6,716,234, the disclosure of which is incorporated by reference herein. The high strength suture may be available in various lengths and widths. FIBREWIRE® suture is formed of an advanced, high-strength fiber material, namely ultra-high molecular weight polyethylene (UHMWPE), sold under the tradenames SPECTRA (Honeywell) and DYNEEMA (DSM), braided with at least one other fiber, natural or synthetic, to form lengths of suture material. The preferred FIBREWIRE® suture includes a core within a hollow braided construct, the core being a twisted yarn of UHMWPE. The suture may optionally include filaments of various colors.

An example method of graft fixation using the pointed tip implant 450 is illustrated with reference to FIGS. 33-35. This exemplary method illustrated in FIGS. 33-35 relates to a specific graft fixation technique (i.e., SUTUREBRIDGE® Lateral Row fixation); however, the invention is not limited to this exemplary embodiment and applies to any other method of soft tissue fixation known in the art.

Referring to FIG. 33, an Arthrex SUTUREBRIDGE® medial row is completed as known in the art and the strands 180 (suture strands 180) are threaded through the titanium eyelet 455. As shown in FIG. 34A, a protective cap 194 (or other device that prevents anchor deployment) is malleted to advance the PUSHLOCK® implant 450 until the anchor 420 contacts bone 193. The suture is then tensioned, as shown in FIG. 34. The protective cap 194 is subsequently removed (FIG. 35A) and the button 420 is malleted until a mark (for example, a predefined laser line) is flush with the bone (FIG. 35). The ribbed, spiked configuration of plug or button 420 facilitates the insertion of the device 400 into the bone by simply exerting force upon the device, without the need to drill or form a hole in the bone.

Although the above embodiments have been described including implants having an aperture of a predefined configuration (e.g., an eyelet or horseshoe configuration), it should be understood that the invention is not limited to these embodiments. Accordingly, the present invention also contemplates implants affixed to or detachable from a preloaded driver and having an aperture of any configuration or geometrical shape that captures suture and allows the captured suture to freely slide within the aperture until the suture is locked in place.

A significant advantage provided by the example methods is that the sutures attached to the graft or the graft itself can be securely attached to the bone without the need to tie knots.

Another advantage achieved by the example embodiments of present invention is that the suture attached to the graft or the graft is secured both along the bottom of the bone socket by the tip of the interference screw or plug, as well as along the sidewall of the socket between the bone and the screw or plug. This arrangement results in a much stronger fixation of the graft to the bone than is achievable with prior art suture anchor procedures.

Although particular embodiments are described above, many other variations and modifications and other uses will become apparent to those skilled in the art who have the benefit of this description. For example, the various features of the example embodiments are not necessarily limited to the particular embodiments shown in the drawings. One or more features of an embodiment may be combined with one or more features of another to realize a different embodiment. Additionally, entirely different embodiments having similar features may be realized. The present invention cannot be limited by the specific disclosure herein, but only by the appended claims.

The invention claimed is:

1. A suture securing assembly, comprising:
an inserter including a distal end, a proximal end, and a longitudinal axis between the distal end and the proximal end;
a first member including an eyelet oriented to thread suture across the longitudinal axis, the first member being situated near the distal end of the inserter, the first member being configured to be placed in bone; and
a second member situated near the distal end of the inserter, the second member being moveable by a portion of the inserter relative to the first member in a distal direction toward the eyelet into a suture securing position where the second member locks suture in place.

2. The assembly of claim 1, wherein
the second member is received on the inserter between the eyelet and the proximal end prior to movement into the suture securing position.

3. The assembly of claim 1, wherein the second member is moveable relative to the first member when the first member is in bone.

4. The assembly of claim 1, wherein
the second member locks the suture in place against an exterior surface of the second member when the second member is in the suture securing position.

5. The assembly of claim 4, wherein
the second member is configured to lock suture in place by wedging suture between the second member and bone.

6. The assembly of claim 5, wherein
the exterior surface of the second member is configured to engage bone to secure the second member in bone.

7. The assembly of claim 1, wherein
the inserter is separable from the first member;
the inserter is separable from the second member; and
the first member and the second member are configured to remain in bone for securing suture in bone.

8. The assembly of claim 1, wherein
the second member comprises a screw.

9. The assembly of claim 1, wherein
the second member comprises a plug.

10. The assembly of claim 1, wherein
the inserter comprises a handle near the proximal end;
a first shaft and a second shaft;
the first shaft facilitates inserting the first member into bone; and
the second shaft facilitates moving the second member into the suture securing position.

11. The assembly of claim 10, wherein
the second shaft is moveable relative to the first shaft for moving the second member into the suture securing position.

12. The assembly of claim 11, comprising
a cap that is moveable relative to the handle and connected with the second shaft for moving the second shaft to cause the second member to move into the suture securing position.

13. The assembly of claim 10, wherein
one of the first shaft or the second shaft is at least partially received within the other of the second shaft or the first shaft.

14. The assembly of claim 1, wherein the first member is a loop of suture defining the eyelet.

15. The assembly of claim 1, wherein the first member is a rigid implant defining the eyelet.

16. A suture securing assembly, comprising:
a driver having a length and a width, the length being greater than the width, the length being parallel to an insertion direction;
a first member supported by the driver, the first member comprising an eyelet that is transverse to the length, the eyelet being configured to allow suture to be threaded through the eyelet transverse to the length, the first member being situated to be moved in the insertion direction to be received in bone; and
a second member supported by the driver, the second member being situated to be moved by a portion of the driver in the insertion direction relative to at least the first member into a suture securing position where the second member locks suture in place.

17. The assembly of claim 16, wherein
the second member is received on a portion of the driver in an initial position; and
the second member is moveable along the portion of the driver in the insertion direction into the suture securing position.

18. The assembly of claim 16, wherein
the driver has a distal end and a proximal end;
the insertion direction corresponds to a direction from the proximal end toward the distal end; and
the first member is situated at least partially beyond the distal end of the driver.

19. The assembly of claim 16, wherein
the second member locks suture in place against an exterior surface of the second member when the second member is in the suture securing position.

20. The assembly of claim 19, wherein
the second member is configured to lock suture in place by wedging suture between the second member and bone.

21. The assembly of claim 20, wherein
the exterior surface of the second member is configured to engage bone to secure the second member in bone.

22. The assembly of claim 16, wherein
the driver is separable from the first member;
the driver is separable from the second member; and
the first member and the second member are configured to remain in bone for securing suture in bone.

23. The assembly of claim 16, wherein
the second member comprises a screw.

24. The assembly of claim 16, wherein
the second member comprises a plug.

25. The assembly of claim 16, wherein
the driver comprises a handle and a rod extending from the handle;
the rod includes a first shaft and a second shaft;
the first shaft facilitates inserting the first member into bone; and
the second shaft facilitates moving the second member into the suture securing position.

26. The assembly of claim 25, wherein
the second shaft is moveable relative to the first shaft for moving the second member into the suture securing position.

27. The assembly of claim 26, wherein
the handle is at least partially moveable relative to at least the first shaft for moving the second shaft to cause the second member to move into the suture securing portion.

28. The assembly of claim 25, wherein
one of the first shaft or the second shaft is at least partially received within the other of the second shaft or the first shaft.

29. The assembly of claim 16, wherein the first member is a loop of suture defining the eyelet.

30. The assembly of claim 16, wherein the first member is a rigid implant defining the eyelet.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 9,179,907 B2
APPLICATION NO. : 14/272601
DATED : November 10, 2015
INVENTOR(S) : Neal S. ElAttrache

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

IN THE CLAIMS:

In claim 27, column 12, line 35; delete "portion" and replace with --position--

Signed and Sealed this
Twenty-ninth Day of March, 2016

Michelle K. Lee

Michelle K. Lee
Director of the United States Patent and Trademark Office